Health Law Advisory: Vermont Passes Sweeping Regulation of Pharmaceutical Marketing Activities

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The Vermont Legislature has passed a law banning many, if not most, industry gifts to prescribers and requiring drug and device manufacturers to publicly disclose any permitted financial relationships with physicians and other health care providers. The law, scheduled to take effect on July 1, 2009, is one of the most stringent state efforts to regulate the marketing of medical products to physicians.

The new legislation expands on the state's existing Pharmaceutical Marketing Disclosure Law, which requires pharmaceutical manufacturers to annually report to the Vermont Attorney General marketing payments made to persons in Vermont who are authorized to prescribe, dispense, or purchase pharmaceutical products.

Broad Gift Ban Prohibition

The legislation imposes a gift ban that prohibits drug, biologics and device manufacturers from offering or giving any gift to a health care provider, which includes a hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe or recommend prescribed products. The term "gift" is broadly defined to include "anything of value provided to a health care provider for free," or "any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider," unless it is an "allowable expenditure." Provided certain requirements are met, the legislation permits payments to health care providers in connection with "significant" educational conferences, bona fide clinical trials, research projects, technical training on use of medical devices, royalties, licensing fees, and other reasonable payments at fair market value.

Specifically exempted from the gift ban prohibition are:

- Samples of prescription drugs intended for distribution to patients;
- Loans of medical devices for short-term trial periods;
- Distribution of scientific or clinical journals to health care providers for the benefit of patients;
- Scholarships or other support for medical students to attend significant educational conferences;
- Rebates and discounts for prescribed products provided in the normal course of business; and
- Labels approved by the federal Food and Drug Administration (FDA) for prescribed products.

Expanded Disclosure Requirements

The law also amends the state's existing public disclosure law to require reporting of the "value, nature, purpose, and recipient information" of all allowable expenditures or gifts by companies to any health care provider with authority to write prescriptions for drugs, medical devices and biologics. The new legislation eliminates the $25.00 reporting threshold in the previous law and also closes a loophole that had allowed companies to keep specific expenses private by claiming them as trade secrets. According to a report last month from Vermont's Attorney General, in 2008, pharmaceutical manufacturers spent $2.9 million on marketing to health care professionals in Vermont. However, of the disclosures reported to the Attorney General, only 17% were available to the public due to the trade secret exemption in the current law.

The required disclosures under the new law do not apply to royalties and licensing fees, rebates and discounts, payments for clinical trials, and samples of prescription drugs intended for distribution to patients. This disclosure exception for sample distribution may not last long, however. The legislation includes a requirement that the Attorney General conduct a review of the advisability of requiring the disclosure of information regarding the provision of free samples.

Trend Toward Transparency

Vermont's legislation is noteworthy because it goes even farther than similar legislation in other states, and because it is part of a broader trend toward transparency in the relationships between health care providers and the drug and device industries.

Minnesota already requires drug companies to report payments to doctors. New Massachusetts regulations limit gifts to health care practitioners and call for the disclosure of any payment or economic benefit worth $50 or more.[1] In 2008, nine states proposed legislation similar to the Massachusetts law. The District of Columbia passed such legislation in 2008, although a portion of the law (Title II) mandating, among other things, the disclosure of drug manufacturer payments to pharmacy benefit managers has since been held to be preempted by the Employee Retirement Income Security Act (ERISA). Title III of the AccessRx Act, however, remains in effect and requires drug manufacturers to report marketing costs for prescription drugs in the District of Columbia.

The potential for a patchwork of onerous state rules has motivated the drug and device industries to lend their support for the Physician Payment Sunshine Act of 2009, sponsored by Senators Charles Grassley (R-Iowa) and Herb Kohl (D-Wisc.).[2] The bill would require manufacturers and group purchasing organizations to disclose all payments or transfers of value to physicians worth $100 or more. Pharmaceutical Research and Manufacturers of America (PhRMA), the Advanced Medical Technology Association (AdvaMed), AstraZeneca, Merck and Eli Lilly have all come out in support of the legislation, but have advocated for a higher threshold reporting requirement and have stressed that the bill must expressly preempt state marketing and reporting laws to ensure consistency in application. As currently drafted, the bill would preempt state disclosure laws, but not state laws that have additional reporting requirements on information not required in the bill.

Industry Response

In addition to voicing support for uniform federal legislation, industry representatives have indicated that state legislation is unnecessary in light of the efforts made by individual companies, trade groups and medical institutions.

To reduce the perception of undue industry influence, PhRMA's voluntary Code on Interactions with Healthcare Professionals prohibits non-educational gifts to physicians and restricts meals.[3] AdvaMed maintains a similar Code of Ethics and plans to publish on its website a list of all companies that have certified their adoption of the Code.

In 2008, several major drug and device manufacturers, including Eli Lilly, Merck and Medtronic, announced that they would voluntarily report certain payments to physicians. Other manufacturers, such as GlaxoSmithKline and Pfizer, not only agreed to report physician payments, but also, in the case of GlaxoSmithKline, to cap such payments at $150,000 per year, and in the case of Pfizer, to eliminate direct financial support for medical education courses offered by third-party companies.

Similarly, medical institutions such as Johns Hopkins, Partners HealthCare and Cleveland Clinic have imposed restrictions on physician interactions with drug and medical device companies. Johns Hopkins bans free drug samples, gifts, entertainment and food, and bars drug and device sales representatives from patient-care areas. Physicians at Partners HealthCare may not accept free meals from or serve on the "speakers' bureaus" of pharmaceutical manufacturers. Free drug samples must be provided through a hospital pharmacy or other central mechanism and sales representatives may not visit staff unless they have "written invitations defining the purpose and terms of visits." Cleveland Clinic plans to publicly report all business relationships between its medical staff and drug and device manufacturers.

Similar to the debate swirling in Congress with respect to health care reform, all of the key stakeholders agree in principle on the goal of greater transparency of the relationships between physicians and drug and device manufacturers, but debate is likely to continue on the methods chosen to achieve this goal.

Endnotes

[1] *See* Mintz Levin Health Law Client Alert "Massachusetts DPH Releases Final Rules for Pharmaceutical and Medical Device Manufacturers' Conduct" and Health Law Client Advisory "Review of the Massachusetts Marketing Code of Conduct for Pharmaceutical and Medical Device Manufacturers."

[2] *See* Mintz Levin Health Law Washington Beat article "Senate Considers Physician Payment Sunshine Act of 2009."

[3] *See* Mintz Levin Health Law Client Alert "PhRMA Issues New Marketing Code Effective January 2009."

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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